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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,433	11/16/2001	Sikander Randhava	13909-00002	6093

7590 02/13/2004

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EXAMINER	
TATE, CHRISTOPHER ROBIN	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/992,433	RANDHAVA ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 16, 2003 has been entered.

Claims 1-23 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 6 are rendered vague and indefinite by the grammatically confusing phrase "wherein said controlled release system consisting essentially of" (lines 4-5 of both claims). It is suggested that the term "consisting" therein be replaced with --consists--.

Claim 11 is rendered vague and indefinite for the same reasoning above with respect to the phrase "An improved oral saw palmetto extract composition consists essentially of" (lines 1-2). It is suggested that the term "consists" therein be replaced with --consisting--.

Claim 4 is rendered vague and indefinite by the phrase "wherein the composition further consists essentially of a therapeutically effective amount of a phytotherapeutic agent" because this phrase is outside the limitations of claim 1 (from which claim 4 depends) – i.e., the product

defined by claim 1 is limited to an oral composition which consists essentially of a therapeutically effective amount of saw palmetto extract, which is closed language with respect to any other active ingredient therein. As such, the oral composition of claim 1 (as drafted) is limited to the active ingredient therein being "saw palmetto extract" and, thus, cannot include an additional active ingredient including the "phytotherapeutic agent" recited in claim 4.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 6-8, and 12-23 stand rejected under 35 U.S.C. 102(e) as being anticipated by Mann (US 6,231,866) for the reasons of record which are restated below.

Mann teaches a controlled release composition comprising saw palmetto extract (termed SAW-MAX) useful for treating BPH, including formulating the composition into a capsule (thus capsulation) which coats/shields the internal bioactive agent from stomach acid degradation so as to release a maximum concentration of bioactive agent to the intestines (see entire document including col 2, lines 3-61; col 5, lines 40-67; col 8, lines 38-49; col 9, line 14 - col 10, line 33). The controlled release composition taught by Mann would inherently initially release saw palmetto extract in the duodenum and before it enters the colon.

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6-8, and 12-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann (US 6,231,866) and Wilding (US 2001/0008638), in view of Locke (US 6,200,573).

Mann is relied upon for the reasons discussed *supra*.

Wilding teaches a controlled release composition (including capsules) comprising saw palmetto extract that comprises two or more enteric coatings, whereby the controlled release formulation may be one of numerous prior art controlled release formulations (see, e.g., page 2, paragraphs 0016-23) including some which would inherently withstand stomach acid degradation and allow release of the saw palmetto extract into the duodenum before entering the colon. In addition, although Wilding does not expressly teach treating BPH via administering the controlled release formulation containing saw palmetto extract, Wilding discloses that the saw palmetto extract is an anti-estrogen ingredient which is useful for treating BPH by decreasing the conversion of testosterone to DHT (see, e.g., page 1, paragraphs 0007- 0008). Further, although Mann does not expressly teach encapsulating the SAW-MAX preparation within an enteric-type coating, Mann does disclose that the SAW-MAX controlled release formulation may optionally be encapsulated (see, e.g., col 10, lines 30-33).

Locke beneficially teaches treating BPH via oral administration of a composition (including a capsule) comprising saw palmetto extract. Locke also beneficially teaches that the composition can be formulated into a once-a-day or even longer sustained release composition using conventional techniques well known in the art (see, e.g., abstract; col 2, lines 4-22; col 3, lines 25-44; col 5, lines 27-42; col 7, line 55 - col 8, line 3; col 9, lines 23-35; and claims).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer one or more of the controlled-release saw palmetto extract-containing compositions taught to a patient suffering from BPH based upon the beneficially teaching provided by Mann and Wilding, as discussed above. The adjustment of particular conventional working conditions (e.g., coating the SAW-MAX formulation of Mann with a conventional enteric coating or other controlled release-type coating; and/or determining a result-effective prior art controlled release formulation in which to incorporate the cited saw palmetto extract compositions so as to effectively release the saw palmetto extracts into the duodenum/small intestines - especially given that Wilding and Locke clearly and advantageously indicate that various types of prior art controlled release formulation technologies can be used to accomplish this controlled-release feature) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1-3, 6-8, and 12-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jia (US 2002/0071869), in view of Mann (US 6,231,866), Wilding (US 2001/0008638), and Locke (US 6,200,573).

The Mann and Wilding references are relied upon for the reasons discussed *supra*.

Jia teaches the incorporation of a biologically active agent such as saw palmetto extract within a bioadhesive preparation so as to protect and target the delivery of the bioactive agent to target cells. Jia also discloses that the bioadhesive composition can be formulated within time-release capsules (see, e.g., pages 1-2, paragraph 0007-0008 and 0018; page 4, paragraphs 0034-0035; and claims).

Locke beneficially teaches treating BPH via oral administration of a composition (including a capsule) comprising saw palmetto extract. Locke also beneficially teaches that the composition can be formulated into a once-a-day or even longer sustained release composition using conventional techniques well known in the art (see, e.g., abstract; col 2, lines 4-22; col 3, lines 25-44; col 5, lines 27-42; col 7, line 55 - col 8, line 3; col 9, lines 23-35; and claims).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate the bioadhesive saw palmetto extract preparation of Jia within a time-release/controlled-release formulation and to treat BPH using such a formulation based upon the beneficial teaching provided by Mann, Wilding, and Locke, with respect to time-release/controlled release saw palmetto extract formulations useful for treating BPH. The adjustment of particular conventional working conditions (e.g., coating the bioadhesive formulation taught by Jia with a conventional enteric coating or other time-release/controlled release-type coating; and/or determining a result-effective prior art controlled release formulation

in which to incorporate the cited saw palmetto extract compositions so as to effectively release the saw palmetto extracts into the duodenum/small intestines - especially given that Wilding and Locke clearly indicate that various types of prior art controlled release formulation technologies can be used to accomplish this controlled-release feature) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicants' arguments with respect to the art rejections above have been carefully considered but are not deemed to be persuasive of error in the rejections.

Applicants argue that the claims, as amended, are not anticipated by Mann because the instant claims are now directed to compositions consisting essentially of saw palmetto extract and a controlled-release formulation, and Mann teaches saw palmetto oil infused into a saw palmetto pomace. However, please note that saw palmetto oil (oil extracted from saw palmetto) as well as saw palmetto pomace (the pulpy refuse removed/extracted from the plant) both properly constitute saw palmetto extracts within the accepted meaning of an herbal extract by one of ordinary skill in the herbal art.

With respect to the U.S.C. 103 rejections above, Applicants have argued and discussed references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which make up the state of the art with regard to the claimed invention. Applicants'

claimed invention fails to patentably distinguish over the state of the art represented by the cited references.

It is strongly suggested that any one of claims 4, 5, 9 or 10 be appropriately incorporated into independent claims 1, 12, and 18 to overcome the art rejections above; and that the cited claims be appropriately amended to overcome the USC 112, second paragraph rejections above.

Conclusion

No claim is allowed.

The prior art previously made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.

Christopher R. Tate
Primary Examiner, Group 1654